**UNITED STATES DISTRICT COURT**
**FOR THE MIDDLE DISTRICT OF GEORGIA**
**ATHENS DIVISION**

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| BASF AGRO B.V., MERIAL LIMITED, and MERIAL SAS<br><br>Plaintiffs,<br><br>v.<br><br>CIPLA LIMITED, *et al*.,<br><br>Defendants, and<br><br>VELCERA, INC. and FIDOPHARM, INC.<br><br>Intervenors. | Civil Case No. 3:07-cv-00125-CDL<br><br>[redacted] |

# EXHIBIT C

**TO INTERVENORS VELCERA, INC. AND FIDOPHARM, INC.'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTIONS FOR TEMPORARY RESTRAINING ORDER AND STATUS CONFERENCE**

[redacted]

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE MIDDLE DISTRICT OF GEORGIA**
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| BASF AGRO B.V., et al.<br>Plaintiffs,<br>v.<br>CIPLA LIMITED, et al.<br>Defendants,<br>and<br>VELCERA, INC. and FIDOPHARM, INC.<br>Intervenors. | Civil Case No. 3:07-CV-00125-CDL<br>[redacted] |

**DECLARATION OF DR. DAVID M. PETRICK**

I, Dr. David M. Petrick, state as follows:

1. I am the Executive Vice President of Research Development and Regulatory Affairs of Velcera, Inc. ("Velcera"), the parent company of FidoPharm, Inc. ("FidoPharm"). I have personal knowledge of the facts set forth in this declaration and, if called upon, could testify truthfully and accurately thereto.

2. [redacted]

3. PetArmor® Plus is referred to in EPA parlance as a "me too" product. "Me too" products are products that are "identical or substantially similar in composition and labeling to a

[redacted]

currently-registered pesticide identified in the application, or that would differ in composition and labeling from such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment." 7 U.S.C. § 136a. "Me too" products have the same active ingredients as a prior EPA approved product, but different inert or inactive ingredients. In order to receive approval as a "me too" product, the inert ingredients typically must be selected from a list of EPA-approved inerts.

4. "Me too" products allow applicants to expedite the review of an EPA application by relying on data from the reference product. The EPA has approved hundreds of "me too" applications through this expedited process, including a multitude of flea and tick treatments for cats and dogs. I am aware of at least ten fipronil-containing flea and tick products that have been approved by the EPA through the "me too" application process. It is a commonly used process that is authorized by Federal statutes and regulations.

5. Under EPA regulations, a "me too" applicant is required to do the following to receive EPA approval for its product:

i) Submit an Application for Pesticide (EPA Form 8570-1);

ii) Submit, via a Confidential Statement of Formula, copies of the old formulations and new formulations (EPA Form 8570-4);

iii) Submit a data matrix (EPA Form 8570-35);

iv) Submit a Certification with Respect to Citation of Data (EPA Form 8570-34);

v) Submit product chemistry data for the new formulations;

vi) Submit documentation for packaging;

vii) Identify an EPA-approved site of manufacturing;

[redacted]

viii) Identify an EPA approved registered active-ingredient establishment;

ix) Submit documentation for approval of a new method of analysis;

x) Submit documentation for approval of a new manufacturing process;

xi) Submit draft labeling;

xii) Submit a statement of Good Laboratory Practices ("GPL"); and

xiii) Register, in each U.S. state, approval to market pesticides.

6. Consistent with the approval process for its old formulations, FidoPharm was required to, and did, follow ***the same*** regulatory path to gain EPA approval for its new formulations. FidoPharm undertook each of the steps described above in paragraph 5, as well as additional steps. All of this work was done without the involvement of Cipla.

7. Specifically, FidoPharm took the following steps, with no involvement from Cipla:

i) [redacted]

ii) [redacted]

iii) [redacted]

iv) [redacted]

v) [redacted]

[redacted]

vi) [redacted]

vii) [redacted]

viii) [redacted]

ix) [redacted]

x) [redacted]

xi) [redacted]

xii) [redacted]

xiii) [redacted]

xiv) [redacted]

xv) [redacted]

8. [redacted]

[redacted]

9. Crystallization inhibitors are, as the name suggests, agents that prevent crystals from forming in solution. In other words, the goal is to prevent the active ingredients (*e.g.,* fipronil and s-methoprene) from precipitating out of solution. Examples of crystallization inhibitors include Nikkol HCO 60, PEG-1000, polyvinylpyrrolidone, and polysorbate 80.

10. Crystallization inhibitors aid in preventing crystallization of fipronil prior to dissemination into the skin surface. If fipronil crystallizes when applied on the skin surface of an animal, this could, for example, negatively affect the aesthetics of the product, which may cause the pet owner to seek a different product.

11. [redacted]

12. [redacted]

[redacted]

[redacted]

13. [redacted]

[redacted]

[redacted]

14. [redacted]

[redacted]

[redacted]

15. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

16. [redacted]

[redacted]

[redacted]

17. [redacted]

18. [redacted]

19. [redacted]

20. [redacted]

[redacted]

[redacted]

[redacted]

21. [redacted]

[redacted]

22. During the approval process, the EPA provided FidoPharm new registration numbers for the new PetArmor® Plus products. EPA registration numbers are specific to the company. LoradoChem had its own EPA company registration number, which is 86230. FidoPharm has its own EPA company registration number, which is 85495. [redacted]

[redacted]

23. I have reviewed the December 14, 2011 letter cited as Exhibit 1 in Merial's Motion. I understand that Merial has told the Court that FidoPharm crossed out LoradoChem's EPA registration number and wrote in its own number. This is incorrect. Exhibit 1 to Merial's motion is a letter from the EPA to FidoPharm, not from FidoPharm to the EPA. *The EPA*, not FidoPharm, crossed the LoradoChem EPA registration number out and wrote in FidoPharm's

[redacted]

registration number. [redacted] Thereafter, in approving the master label on December 14, the EPA handwrote the new approved registration number on FidoPharm's master label submission. In fact, it is obvious on the face of the document that the EPA made the handwritten change. The stamp on the bottom right side of page 3 of Exhibit 1 is the EPA's stamp indicating its acceptance of the submission with comments. The handwriting of the numbers on that stamp, which came from the EPA, is clearly the same handwriting as the numbers on the cross out.

24. [redacted]

25. FidoPharm received EPA approval for its new pipette, labeling, and child resistant packaging on December 14, 2011. Merial Ex. 1.

26. [redacted]

27. [redacted]

[redacted]

28. [redacted]

29. I understand that Merial has told the Court that FidoPharm gained EPA approval for its PetArmor® Plus products in three months. This is incorrect. [redacted]

30. [redacted]

31. In sum, Cipla has had no involvement whatsoever in the development, manufacture, and/or packaging of FidoPharm's new PetArmor® Plus products.

[redacted]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed at Yardley, Pennsylvania this 30th day of April, 2012.

Dr. David M. Petrick

**HIGHLY CONFIDENTIAL INFORMATION—ATTORNEYS' EYES ONLY**

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# EXHIBIT 1

**TO DR. DAVID M. PETRICK'S DECLARATION**
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# EXHIBIT 2

**TO DR. DAVID M. PETRICK'S DECLARATION**
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# EXHIBIT 3

**TO DR. DAVID M. PETRICK'S DECLARATION**
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